REMARKS

The Office Action of September 15, 2005, has been received and reviewed. Claims 1-21 are currently pending in the application. Claims 1-21 stand rejected. Claims 2-13 have been cancelled. Claims 1 and 14-21 have been amended as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. It is respectfully submitted that no new matter is believed to have been entered. Reconsideration is respectfully requested.

Priority

The Office Action indicated that a certified copy of the EP 98202297.2 application has not been received. Applicants' representatives have requested a certified copy of the EP 98202297.2 application which will be submitted to the Patent Office as soon as it is received.

Objections to the Drawings

FIGS. 1, 4 and 5 were objected to "because they fail to show any details." (*See*, Office Action of September 15, 2004, hereinafter referred to as the "Office Action," at page 2). Replacement copies of FIGS. 1, 4 and 5 are submitted herewith to address the objections. Replacement FIGS. 1, 4 and 5 contain no new subject matter. Withdrawal of the objections to FIGS. 1, 4 and 5 is requested.

Double Patenting Rejection Based on U.S. Application No. 10/318,675

Claims 1-5 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as assertedly being unpatentable over claims 1-5 of copending U.S. Application 10/381,088. As this is a provisional rejection, applicants will address the rejections upon an indication of allowable subject matter.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-21 stand rejected under 35 U.S.C. § 112, second paragraph, for assertedly "failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (Office Action at page 2). Claims 2-13 have been cancelled rendering the

rejections thereof moot. Partly in view of the amendments to claims 1 and 14-21, reconsideration and withdrawal of the indefiniteness rejections are requested.

Specifically, it was asserted that with respect to claim 1, the metes and bounds of the phrase "includes a tropism for dendritic cells" is unclear. (Office Action at page 4). Though applicants do not agree with the asserted rejection, the phrase has been removed from amended claim 1.

It was also asserted that claims 2-4 and 8-21 were vague and indefinite in that the metes and bounds of "providing a recombinant adenoviral vector" were unclear. (*Id.* at page 5). Although applicants do not agree with the asserted rejections, the phrase "providing a recombinant adenoviral vector" has been removed from amended claims 14-21 and, as previously stated, claims 2-4 and 8-13 have been canceled. Further, claims 14-19 have been amended to recite in part the method according to claim 1, wherein the recombinant adenoviral vector of subgroup C origin is of a serotype 5 origin. Thus, one of ordinary skill in the art would understand the methods of amended claims 14-21.

With regard to claims 8-19, it was thought that the phrase "based on" was unclear. (Office Action at page 5). The rejection is mooted because the phrase "based on" has been removed from amended claims 14-19, and claims 8-13 have been canceled.

It was also asserted that claims 8 and 14 were vague and indefinite because the metes and bounds of "the part of a non-native fiber protein" that is selected from fiber proteins are unclear. (*Id.*). Claim 8 has been canceled and the phrase "the part of a non-native fiber protein" has been removed from amended claim 14. Thus, one of ordinary skill in the art would understand the method of amended claim 14.

Reconsideration and withdrawal of the indefiniteness rejections of claims 1 and 14-21 are requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 2, 3, and 8-21 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly "failing to comply with the written description requirement." (Office Action at page 5). Specifically, it was asserted that the claims "contain subject matter, which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (*Id.*). Claims 2-13 have been cancelled rendering the rejections thereof moot. Applicants traverse the remaining written description rejections as hereinafter set forth.

The Office Action asserts that claims 14-19 lack written description for "parts" of fiber proteins from a first or other adenoviral serotypes. (*Id.* at page 7). The rejection is mooted because the term "parts" of fiber proteins has been removed from amended claims 14-19. Further, claim 14 has been amended to recite in part wherein the recombinant adenoviral vector of subgroup C origin is of a serotype 5 origin. Claims 15-19 have been similarly amended. Support for this language can be found in the as-filed specification, *inter alia*, at paragraphs **[0024]** and **[0042]**.

Additionally, the Office Action asserts that "there is no correlation between 'at least parts' of fiber proteins and their ability to direct tropism for DCs or to reduce the tropism for liver cells." (Office Action at page 7). Although applicants do not agree with the rejection, to expedite prosecution, the reference to parts of fiber proteins and their ability to direct tropism for liver cells have been removed from the claims.

Claim 20 is rejected for assertedly lacking written description for the phrase, "replication of the recombinant adenoviral vector's genome in a target cell is at least partly reduced in comparison to a wild-type adenovirus." (*Id.*). Since the as-filed specification discloses that "the capacity of the adenoviral nucleic acid to replicate in a target cell has been reduced or disabled" at paragraph **[0043]** in the as-filed specification, one of ordinary skill in the art could only conclude that the inventors were in possession of the method of amended claim 20. (*See* Specification at paragraph **[0043]**).

Claim 21 is rejected for lacking written description for the phrase "an immune response to the recombinant adenoviral vector in a host is at least partly reduced in comparison to a wild-type adenovirus." (Office Action at page 7). The as-filed specification discloses "that the capacity of a host immune system to mount an immune response against adenoviral proteins encoded by the adenovirus nucleic acid has been reduced or disabled." (Specification as-filed,

paragraph **[0043]**). Thus, one of ordinary skill in the art would conclude that the inventors are in possession of the method of amended claim 21.

Reconsideration and withdrawal of the written description rejections of claims 14-21 are requested.

Enablement

Claims 1-21 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement "for delivering heterologous nucleic acid to dendritic cells *in vivo*." (Office Action at page 8). Claims 2-13 have been cancelled rendering the rejections thereof moot. Applicants traverse the remaining enablement rejections as hereinafter set forth.

Although applicants do not agree that any of the claims lack enablement, claim 1 has been amended to recite in part a method for delivering a heterologous nucleic acid to a dendritic cell *in vitro*, wherein the method includes providing a recombinant adenoviral vector of a subgroup C origin. In amended claim 1, the recombinant adenoviral vector includes a chimeric coat having a fiber protein, wherein at least a fiber shaft and a fiber knob of the fiber protein is of an adenovirus of a serotype selected from the group consisting of 11, 16, 35, 40-L and 51.

As stated in M.P.E.P. § 2106.C, "[c]laims and disclosures are not to be evaluated in a vacuum. If elements of an invention are well known in the art, the applicant does not have to provide a disclosure that describes those elements." The parent application of the instant application (US Patent Application Publication 20030017138) specifically discloses how to make a chimeric coat having fiber proteins. For instance, the parent application discloses the production of a fiber chimeric library produced using a NdeI site that is present in the part of the fiber gene that encodes the tail region of the fiber of Ad5. (*See, Id.* at FIG. 6). Thus, the first part of the fiber gene up to the NdeI site is of a subgroup C (*i.e.*, Ad5) origin, while the remaining part of the tail and the shaft of the knob are of another serotype, such as serotype 11, 16, 35, 40-L or 51. (*See, Id.*; *see also* Specification as-filed, paragraph **[0046]**). Thus, one of ordinary skill in the art would be able to make the recombinant adenoviral vector of the method of amended claim 1.

The as-filed specification also discloses how to use the recombinant adenoviral vector of amended claim 1 to deliver a heterologous nucleic acid to a dendritic cell *in vitro*. The as-filed

specification, at paragraph **[0046]**, states that "alteration of the Ad5 host cell range to be able to target DCs *in vitro* as well as *in vivo* is a major interest of the invention." Further, the as-filed specification discloses multiple working examples of recombinant adenoviral vectors that deliver a heterologous nucleic acid to a dendritic cell *in vitro*. For instance, Examples I-XII, at paragraphs **[0049]-[0066]** disclose the production of Ad5/chimeric vectors having a cell type specificity for dendritic cells. Further, Example IV discloses a working example of the delivery of a heterologous nucleic acid (*e.g.*, GFP as a marker gene) to dendritic cells *in vitro* and Example VI discloses the delivery of a heterologous nucleic acid (*e.g.*, a luciferase transgene) to dendritic cells *in vitro*. (*See also*, Examples VII, VIII, IX, X, XI and XII of the as-filed specification). Therefore, one of ordinary skill in the art would be able to make and use the method of amended claim 1.

Dependent claims 14-21 are enabled, *inter alia*, as depending from an enabled base claim, amended claim 1.

Reconsideration and withdrawal of the enablement rejections of claims 1 and 14-21 are requested.

Rejections Under 35 U.S.C. § 102(e)

Claims 1 and 20 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by O'Riordan et al (U.S. Patent Application Patent 6,287,857, hereinafter referred to as "O'Riordan"). Applicants traverse the anticipation rejections as hereinafter set forth.

Claims 1 and 20 cannot be anticipated since O'Riordan does not, expressly or inherently, disclose each and every element of amended claim 1. Amended claim 1 recites in part providing a recombinant adenoviral vector of a subgroup C origin, the recombinant adenovirus vector comprising a chimeric coat having a fiber protein, wherein at least a fiber shaft and a fiber knob of the fiber protein is of an adenovirus of a serotype selected from the group consisting of 11, 16, 35, 40-L and 51. Amended claim 1 cannot be anticipated since O'Riordan does not disclose a recombinant adenovirus having a chimeric coat comprising a fiber protein, wherein at least a fiber shaft and a fiber knob of the fiber protein is of an adenovirus of a serotype selected from the group consisting of adenoviral serotypes 11, 16, 35, 40-L and 51. (*See*, O'Riordan at columns

36-47). Thus, O'Riordan does not describe each and every element of amended claim 1 as required for anticipation.

Dependent claim 20 is allowable, *inter alia*, as depending from an allowable base claim (*i.e.*, amended claim 1).

Reconsideration and withdrawal of the anticipation rejection of claims 1 and 20 are requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 3-10, 12-17, 19 and 21 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over O'Riordan in view of Crystal et al (U.S. Patent 6,127,525, hereinafter referred to as "Crystal"). Claims 2-13 have been cancelled rendering the rejections thereof moot. Applicants traverse the remaining obviousness rejections as hereinafter set forth.

A *prima facie* case of obviousness cannot be established since O'Riordan does not, alone, or in combination with Crystal, teach or suggest each and every element of any of amended claims 14-17, 19, and 21.

Claims 14-17, 19 and 21 depend from amended claim 1 and, therefore, include the elements of amended claim 1. As previously established herein, O'Riordan does not disclose a recombinant adenovirus vector having a chimeric coat, wherein the chimeric coat includes a fiber protein having at least a fiber shaft and a fiber knob of adenoviral serotypes 11, 16, 35, 51, and 40-L, as recited in amended claim 1. Further, Crystal does not teach or suggest the chimeric coat including a fiber protein having at least a fiber shaft and a fiber knob of adenoviral serotypes 11, 16, 35, 51, and 40-L as recited in amended claim 1. Since O'Riordan and Crystal do not teach or suggest all of the elements of amended independent claim 1 and claims 14-17, 19 and 21 include the elements of amended claim 1, O'Riordan and Crystal also cannot teach or suggest all of the elements of claims 14-17, 19 and 21 as required to establish a *prima facie* case of obviousness.

Reconsideration and withdrawal of the obviousness rejections of claims 14-17, 19 and 21 are requested.

CONCLUSION

In view of the foregoing amendments and remarks, the claims define patentable subject matter and a notice of allowance is requested. If any questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

Andrew F. Nilles
Registration No. 47,825
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922
FAX: 801-531-9168

Date: January 18, 2005

IN THE DRAWINGS:

Accompanying this Amendment are the attached sheets of drawings which replace FIGS. 1, 4 and 5. These sheets replace the original sheets including FIGS. 1, 4 and 5. No new matter has been added.